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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,561	03/27/2001	Larry L. Hood	155694-0054	2600
1622	7590	12/29/2005		EXAMINER
IRELL & MANELLA LLP				SHAY, DAVID M
840 NEWPORT CENTER DRIVE				
SUITE 400			ART UNIT	PAPER NUMBER
NEWPORT BEACH, CA 92660			3735	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/819,561	HOOD, LARRY L.	
	<b>Examiner</b>	<b>Art Unit</b>	
	david shay	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on October 5, 2005.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-34 and 36-59 is/are pending in the application.  
 4a) Of the above claim(s) 5-34, 39, 48, 49, 52 and 55-59 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-4, 36-38, 40-47, 50, 51, 53, and 54 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

Applicant argues that the laser of Bille et al, which changes the tissue into a “semi-liquid” state, does not denature the tissue. To rebut this argument applicant has included two declarations from ophthalmologists. Both declarations read, in the substance of the statement of facts regarding the disputed term (i.e. “denature”), they will be treated together. The Declarations both state the Declarants’ qualifications as ophthalmologists and state a disagreement with the examiner’s, opining that the method of Bille ‘is not “denaturing: tissue in the context of the above entitled application.’ However, neither Declaration identifies the particular “context” provided in the application which would lead the Declarants to presume a definition of the term “denature” different from that clearly provided by a dictionary specific to the field of medicine. The Declarations also reproduce arguments set forth by applicant’s representative, which includes the statements: “The claimed process provides enough energy to change the helical tissue structure without creating damage that causes the body to repair the denatured area”; “Changing the helical structure modifies the refractive power of the cornea.”; and “Changing the tissue to a semi liquid state will cause the body to repair the tissue back to the original state.” The examiner will take these statements one at a time. The first statement regarding the changing of the helical structure is noted, however, the originally filed specification is completely devoid of any discussion of such “helical structures”. The second statement, which appears to indicate that these structures are somehow involved with the refractive index of the tissue, is noted, however, it is noted that since the liquification of tissue of Bille is described as providing a refractive change, it would appear that the liquification portion of the method of Bille does, alter these “helical structures” and thus would qualify as a method for “denaturing” tissue. Lastly, as the patent of Bille not only teaches, but claims the correction

of refractive errors by liquefying the tissue, the simple opinions of applicant's representative, and Declarants' assent thereto are insufficient to overcome the presumed validity of the Bille patent. Thus these arguments are not convincing.

Claims 55-58 are indefinite because the preamble recites a method, but they depend from an apparatus claim (claim 52). For the purposes of examination, these claims will be treated as depending from claim 53.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 45-47, 51, 53 and 54 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bille et al.

Claims 1-3, 36-38, 40, 42, 45-47, 51, 53 and 54 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Spears et al.

Claims 1-4 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bille et al in combination with Knopp et al. Bille et al teaches denaturing tissue. Knopp et al disclose a medical system that can denature a cornea comprising laser (item 87), a stepper motor (item 41), and a lens (items 17 and 23). It would have been obvious to employ the laser of Bille et al in the device of Knopp et al, since this provides recurvature without affecting surface tissue, as taught by Bille et al or to employ the focal point displacement mechanism of Knopp et al, since Bille et al provides no particulars of the mechanisms for moving the beam, thus producing a device such as claimed.

Claims 36-38 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bille et al in combination with Klopotek. Bille et al teaches denaturing eye tissue. Klopotek teaches

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configuring the intensity of an incident laser beam. It would have been obvious to the artisan of ordinary skill to employ the laser of Bille et al in the device of Klopotek, since this provides a non destructive recurvature or to employ the intensity configuring mask of Klopotek in the device of Bille et al, since it will work equally well with any laser, thus producing a device such as claimed.

Claims 1, 40, 41, 45 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knopp et al in combination with Bille et al, as applied to claims 1-4 and 40 are above, and further in view of L'Esperance Jr. L'Esperance Jr. teaches an ocular surgery device which provides for the movement of the beam focal point in a circular pattern about the cornea at a predetermined diameter. It would have been obvious to the artisan of ordinary skill to employ a scanner with a scan pattern as taught by L'Esperance, Jr., since this is a useful pattern for ophthalmic surgery and to produce the pattern with the diameter of 6-8 millimeters, since L'Esperance, Jr. says only that the distance needs to be "predetermined" and using a distance of 6-8 millimeters would place it outside of the optically used portion of the cornea, which will prevent visual distortions as is notorious in the art, thus producing a device such as claimed.

Claims 1, 40, 41, 45 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knopp et al in combination with Bille et al, as applied to claims 1-4 and 40 are above, and further in view of L'Esperance Jr. L'Esperance Jr. teaches an ocular surgery device which provides for the movement of the beam focal point in a circular pattern about the cornea at a predetermined diameter. It would have been obvious to the artisan of ordinary skill to employ a scanner with a scan pattern as taught by L'Esperance, Jr., since this is a useful pattern for ophthalmic surgery and to produce the pattern with the diameter of 6-8 millimeters, since

L'Esperance, Jr. says only that the distance needs to be "predetermined" and using a distance of 6-8 millimeters would place it outside of the optically used portion of the cornea, which will prevent visual distortions as is notorious in the art, thus producing a device such as claimed.

Claims 37 and 42-44 are rejected under 35 U.S.C 103(a) as being unpatentable over Bille et al in combination with Klopotek as applied to claims 36-38 and 42 above, and further in view of L'Esperance, Jr. L'Esperance, Jr. teaches providing a circularly scanned spot, which denatures tissue. Thus it would have been obvious to the artisan of ordinary skill to employ the intensity modifier of Klopotek to produce the intensity pattern of the spot in the method of L'Esperance, Jr. since the outputs of laser such as used by L'Esperance, Jr. have a non-uniform intensity distribution, thus producing a method such as claimed.

Applicant's arguments filed October 5, 2005 have been fully considered but they are not persuasive. The arguments are not convincing for the reasons set forth above.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam, can be reached on Monday, Tuesday, Wednesday, and Thursday at (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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